K070928

AUG - 1 2007

Premarket Notification 510(k) Summary

1.0 Submitter Information

Company Name	Plus Orthopedics AG
Company Address	Erlenstraße 4a CH-6343 Rotkreuz Switzerland
Contact Name	Pamela J. Weagraff, Principal Consultant Quintiles Consulting
Contact Address	18 Bridie Lane Norfolk, MA 02056
Contact Telephone	508-528-1745
Contact Facsimile	978-752-1225
Contact E-mail	pamela.weagraff@quintiles.com

2.0 Date Prepared: June 8, 2007

3.0 Name of Device

3.1 Device Name: Ceramic Ball Heads, various sizes

3.2 Common Name: Ceramic Ball Heads

3.3 Classification Name and Reference: Hip Joint Metal/Ceramic/Polymer Semi-constrained Cemented or Nonporous Uncemented Prosthesis, Title 21 CFR Part 888.3353

4.0 Substantial Equivalence Claimed to Predicate Device

Portland Ceramic (BIOLOX® *forte*), K061564
Need to add CoCrMo taper predicate used with Portland

5.0 Device Description

The Plus Orthopedics' Ceramic Ball Heads are intended for mechanical fixation to a mating hip stem and indicated for treatment of patients who are candidates for primary and revision total hip arthroplasty where the hip joint needs restructuring due to disease or trauma. These devices are intended to aid the surgeon in relieving the patient of hip pain and restoring hip motion.

These ceramic ball heads are to be used only with hip stems manufactured by Plus Orthopedics AG, specifically SL-PLUS®/SLR- PLUS®, SL- PLUS® Lateral, Modular- PLUS® and IPM stem. Manufactured by CeramTec AG, the Ceramic Ball Heads are made of BIOLOX® *forte*, a high purity aluminum oxide per ISO 6474, with a small amount of magnesium to prevent grain growth. The Ceramic Ball Heads are available in various sizes from 28, 32 up to 36 mm, in small medium and large for each.

6.0 Indications for Use

The Plus Orthopedics AG Ceramic Ball Heads are intended for mechanical fixation to a mating hip stem and indicated for treatment of patients who are candidates for primary and revision total hip arthroplasty where the hip joint needs restructuring due to disease or trauma. These devices are intended to aid the surgeon in relieving the patient of hip pain and restoring hip motion. Please note that the patient should be skeletally mature and the patient's condition should be due to the following:

1. Osteoarthritis
2. Rheumatoid arthritis
3. Tumor conditions involving the upper third of the femur of the Acetabular
4. Ankylosing spondylitis
5. Psoriatic arthritis
6. Old osteomyelitis – with a long infection-free period and a normal WBC. ESR and C-reactive protein
7. Non-union of femoral neck fracture or avascular necrosis of the femoral head
8. Post-traumatic fracture/dislocation of the hip
9. Revision of an unsuccessful arthrodesis with either poor positioning or pain in the hip, or where low back pain or knee pain is becoming disabling
10. Revision of an unsuccessful cemented or un-cemented hip replacement, providing sufficient bone stock is present
11. Revision of a previous unsuccessful osteotomy, Girdlestone resection, cup arthroplasty or hemi-arthroplasty.

These ceramic ball heads are to be used only with hip stems manufactured by Plus Orthopedics AG, specifically SL-PLUS®/SLR- PLUS®, SL- PLUS® Lateral, Modular- PLUS® and IPM stem.

7.0 Predicate Device Comparison of Indications for Use / Intended Use and Technical Characteristics

The comparison of the Ceramic Ball Heads was based on a review of the Design Control documentation, relevant aspects of which are included in the company's 510(k) Premarket Notification, and information concerning the predicate device that was obtained from the FDA web site. The comparison considered technical characteristics and the indications for use / intended use.

8.0 Performance Data

8.1 Performance Standards: no performance standards applicable to this device, Hip Joint Metal/Ceramic/Polymer Semi-constrained Cemented or Nonporous Uncemented Prosthesis, Title 21 CFR Part 888.3353; Product Code: LZO, have been adopted under Section 514 of the Food Drug and Cosmetic Act.

8.2 The Ceramic Ball Heads comply with the following FDA recognized standards:

8.2.1 ISO 6474:1994, Implants for surgery -- Ceramic materials based on high purity alumina

8.2.2 ISO 7206-10, 2003, Implants for surgery -- Partial and total hip-joint prostheses -- Part 10

8.2.3 AAMI / ANSI / ISO 11137:1994, Sterilization of health care products - Requirements for validation and routine control -- radiation sterilization and ANSI/AAMI/ISO 11137:1994 (Amendment 1:2002).

8.3 Performance Testing: Design verification and design validation, e.g., bench testing was performed according to FDA's Design Control Requirements, Title 21 Code of Federal Regulations, Part 820.30.

9.0 Conclusion

The information and data provided in this 510(k) Premarket Notification establish that the Ceramic Ball Heads, various sizes, are substantially equivalent to the afore-mentioned predicate device with respect to indications for use/intended use, and technical characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 1 2007

Plus Orthopedics AG
% Ms. Pamela Weagraff
Principal Consultant
18 Bridie Lane
Norfolk, Massachusetts 02056

Re: K070928
Trade/Device Name: Ceramic Ball Heads, 28, 32 and 36 mm
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint, metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: II
Product Code: LZO
Dated: March 30, 2007
Received: April 3, 2007

Dear Ms. Weagraff:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

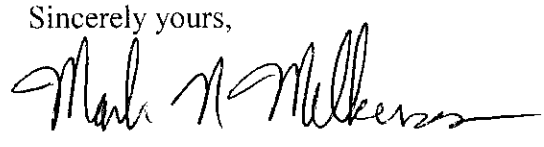
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ODE Indications for Use Statement

510(k) Number (if known): K070928

Device Name: Ceramic Ball Heads, 28, 32 and 36 mm

Indications for Use:

The Plus Orthopedics' Ceramic Ball Heads are intended for mechanical fixation to a mating hip stem and indicated for treatment of patients who are candidates for primary and revision total hip arthroplasty where the hip joint needs restructuring due to disease or trauma. These devices are intended to aid the surgeon in relieving the patient of hip pain and restoring hip motion. Please note that the patient should be skeletally mature and the patient's condition should be due to the following:

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Prescription Use: ___X___ AND/OR Over-the-Counter Use: _____
(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K070928